

## PATENT COOPERATION TREATY

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo:  
JANE MASSEY LICATA  
LICATA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053Docket System  
Status Report  
Docket Book*entered US nat'l  
phase***PCT**NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)**20 SEP 2005**

Applicant's or agent's file reference

UMD-0015

**IMPORTANT NOTIFICATION**

International application No.

PCT/US03/34683

International filing date (day/month/year)

31 October 2003 (31.10.2003)

Priority date (day/month/year)

20 December 2002 (20.12.2002)

Applicant

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Elizabeth Slobodyansky, PhD

Telephone No. 571-272-1600

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference UMD-0015	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/34683	International filing date (day/month/year) 31 October 2003 (31.10.2003)	Priority date (day/month/year) 20 December 2002 (20.12.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 1/21, 9/28, 15/52; C12Q 1/34, 1/68; C07H 21/04; A61K 38/47 and US Cl.: 536/23.2, 23.4; 435/4, 6, 22, 202, 252.3, 252.5, 440; 424/94.61		
Applicant UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>—</u> sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 20 July 2004 (20.07.2004)	Date of completion of this report 01 August 2005 (01.08.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Valerie Bell-Harris</i> Elizabeth Slobodyansky, PhD Telephone No. 571-272-1600	

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/34683

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:
  - pages 1-45 as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the claims:
  - pages 46-50, as originally filed
  - pages NONE, as amended (together with any statement) under Article 19
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the drawings:
  - pages 1, as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:
  - pages 1-10, as originally filed
  - pages NONE, filed with the demand
  - pages NONE, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 5-7

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-7 are so unclear that no meaningful opinion could be formed (*specify*):

because they are improper multiple dependent claims under PCT Rule 6.4(a)

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)	Claims <u>2, 3, 9, 12-14, 16, 18, 19, 26-34</u>	YES
	Claims <u>1, 4, 8, 10, 11, 15, 20-25</u>	NO
Inventive Step (IS)	Claims <u>2, 3, 9, 16, 18, 19, 32-34</u>	YES
	Claims <u>1, 4, 8, 10-15, 17, 20-31</u>	NO
Industrial Applicability (IA)	Claims <u>1-4, 8-34</u>	YES
	Claims <u>NONE</u>	NO

### 2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Claims 1, 4, 8, 11 and 15 lack novelty under PCT Article 33(2) as being anticipated by Graham et al.

Graham et al teach an isolated nucleic acid sequence encoding  $\beta$ -N-Acetylhexosaminidase A (i.e.  $\beta$ -N-acetylglucosaminidase) from *Dictyostelium discoideum* and the encoded purified enzyme (page 16823, 1<sup>st</sup> column; page 16824, 1<sup>st</sup> column, 2<sup>nd</sup> full paragraph). The amino acid sequence (532 amino acids) is 12.5% identical to SEQ ID NO:2. They teach that this enzyme is a lysosomal enzyme. They teach a solution of pH6.5 comprising the enzyme (page 16824, 2<sup>nd</sup> column) that can be considered as a pharmaceutical composition or a liquid antiseptic solution comprising thereof.

Claims 1, 4, 8, 11 and 15 lack novelty under PCT Article 33(2) as being anticipated by Somerville et al.

Somerville et al teach an isolated nucleic acid sequence encoding  $\beta$ -N-acetylhexosaminidase from *Vibrio vulnificus* and the encoded purified enzyme (page 6751; page 6753). The amino acid sequence (847 amino acids) is 11.6% identical to SEQ ID NO:2. They teach a solution of expressed enzyme (page 6751, 2<sup>nd</sup> column) that can be considered as a pharmaceutical composition or a liquid antiseptic solution comprising thereof.

Claims 1, 4, 8, 10, 11 and 15 lack novelty under PCT Article 33(2) as being anticipated by Clarke et al.

Clarke et al teach an isolated nucleic acid sequence encoding  $\beta$ -N-Acetylglucosaminidase from *Streptococcus pneumoniae* and the encoded purified enzyme (page 8805). They teach a fusion protein comprising said enzyme (page 8806, 1<sup>st</sup> column, last paragraph; page 88111, Table 3). The amino acid sequence (1312 amino acids) is 13.6% identical to SEQ ID NO:2. They teach a solution comprising the enzyme that can be considered as a pharmaceutical composition or a liquid antiseptic solution comprising thereof.

Claims 1, 4, 8, 15 and 20-25 lack novelty under PCT Article 33(2) as being anticipated by Convents et al.

Convents et al teach an isolated nucleic acid sequence encoding hexosaminidase of 847 amino acids (SEQ ID NO:5) that is 11.6% identical to SEQ ID NO:2. They teach the laundry and cleaning antimicrobial compositions comprising said enzyme (pages 1, 2, 6).

Claims 10, 12-14, 17 and 20-31 lack an inventive step under PCT Article 33(3) as being obvious over Graham et al alone or in view of Convents et al.

The teachings of Graham et al and Convents et al are outlined above. It would have been obvious to one of ordinary skill in the art to prepare the enzyme taught by Graham et al as a fusion protein with an affinity purification tag and to use the enzyme in various antimicrobial preparations and methods.

Claims 10, 12-14, 17 and 20-31 lack an inventive step under PCT Article 33(3) as being obvious over Somerville et al in view of Convents et al.

The teachings of Graham et al and Convents et al are outlined above. It would have been obvious to one of ordinary skill in the

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/34683

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

art to prepare the enzyme taught by Somerville et al as a fusion protein with an affinity purification tag and to use the enzyme in various antimicrobial preparations and methods.

Claims 12-14, 17 and 20-31 lack an inventive step under PCT Article 33(3) as being obvious over Clarke et al in view of Convents et al. The teachings of Clarke et al and Convents et al are outlined above. It would have been obvious to one of ordinary skill in the art to use the enzyme taught by Clarke et al in various antimicrobial preparations and methods.

Claims 10, 12-14, 17 and 26-31 lack an inventive step under PCT Article 33(3) as being obvious over Convents et al. The teachings of Convents et al are outlined above. It would have been obvious to one of ordinary skill in the art to prepare the enzyme taught by Convents et al as a fusion protein with an affinity purification tag to use the enzyme taught by Convents et al in various pharmaceutical antimicrobial preparations and treatment methods.

Claims 2, 3, 16, 18, 19 and 32-34 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest N-acetylglucosaminidase of SEQ ID NOs: 2, 4, 6, 8 or 10 and a nucleic acid encoding thereof. The prior art does not teach or fairly suggest mutant of *Actinobacillus actinomycetemcomitans* having mutated *dspB* gene and a method of use thereof.

Claims 1-4 and 8-34 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
JANE MASSEY LICATA  
LICATA & TYRRELL P.C.  
66 E. MAIN STREET  
MARLTON, NJ 08053

## PCT

COMMUNICATION IN CASES FOR WHICH  
NO OTHER FORM IS APPLICABLE

Date of Mailing  
(day/month/year)

**20 SEP 2005**

Applicant's or agent's file reference

UMD-0015

**REPLY DUE**

see paragraph 1 below

International application No.

PCT/US03/34683

International filing date

(day/month/year) 31 October 2003 (31.10.2003)

Applicant

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

1. ☐ REPLY DUE within \_\_\_\_ months/days from the above date of mailing

☒ NO REPLY DUE

2. COMMUNICATION:

Ms. Jany Licata agreed to accept form PCT-409 containing the negative statements in lieu of form PCT-408.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/ US  
Commissioner for Patents  
P.O. Box 1450  
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Facsimile No. (703) 305-3230

Authorized officer

*Valerie Bell-Hawson*  
Elizabeth Slobodyansky, PhD

Telephone No. 571-272-1600



# PATENT COOPERATION TREATY

## PCT

### NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/34683	Applicant's or agent's file reference UMD-0015	Date of informal communication (day/month/year) 01 August 2005 (01.08.2005)
Applicant UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY		

<u>Communication</u>  <input checked="" type="checkbox"/> by telephone  <input type="checkbox"/> personal	<table style="width: 100%;"> <tr> <td style="width: 30%;"><u>Participants</u></td> <td style="width: 30%; text-align: center;"><input checked="" type="checkbox"/> Identity checked</td> <td style="width: 30%; text-align: center;"><input checked="" type="checkbox"/> authorization checked</td> <td style="width: 10%; text-align: center;"><input type="checkbox"/> personally known</td> </tr> <tr> <td><input type="checkbox"/> Applicant:</td> <td colspan="3">UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY</td> </tr> <tr> <td><input checked="" type="checkbox"/> Agent:</td> <td colspan="3">Jane Licata</td> </tr> <tr> <td><input checked="" type="checkbox"/> Examiner(s):</td> <td colspan="3">Elizabeth Slobodyansky</td> </tr> </table>	<u>Participants</u>	<input checked="" type="checkbox"/> Identity checked	<input checked="" type="checkbox"/> authorization checked	<input type="checkbox"/> personally known	<input type="checkbox"/> Applicant:	UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY			<input checked="" type="checkbox"/> Agent:	Jane Licata			<input checked="" type="checkbox"/> Examiner(s):	Elizabeth Slobodyansky		
<u>Participants</u>	<input checked="" type="checkbox"/> Identity checked	<input checked="" type="checkbox"/> authorization checked	<input type="checkbox"/> personally known														
<input type="checkbox"/> Applicant:	UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY																
<input checked="" type="checkbox"/> Agent:	Jane Licata																
<input checked="" type="checkbox"/> Examiner(s):	Elizabeth Slobodyansky																

Summary of communication:

Ms. Licata agreed to accept IPER (form PCT-409) in lieu of Written Opinion (form PTO-408) even if it will contain the negative statements.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US  
 Mail Stop PCT, Attn: IPEA/ US  
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Authorized officer  
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 Elizabeth Slobodyansky, PhD  
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